

## REMARKS

Claims 1-27 were previous pending. Claim 27 has been cancelled. New claims 28-30 have been added. Therefore, claims 1-26 and 28-30 will be pending upon entry of current amendments. Claims 1, 2, 3, 7-15, and 25 have been amended. The amendments to claim 1 are at least supported by the disclosures in page 12, lines 24-27; page 7, lines 1-4; and page 22, lines 18-21 and lines 24-25. The dispersion of solid particles of pharmacological agent which retain their solid particulate form in the melt processing temperature of the matrix is disclosed in the description in page 12, lines 24-27. The production of cavities around the particles of the pharmacological agent as a result of orientation and mechanical solid-state processing of the mixture of the matrix and said particles is presented in page 7, lines 1-4 and page 22, lines 18-21 and lines 24-25. The amendments to claims 2, 3, 7-15, and 25 are at least supported by the disclosures in Example 2, page 19, line 30 to page 22, line 8 of the specification. Support for new claim 28 can be found in page 7, lines 12-15. Support for new claim 29 can be found in Example 2, page 19, line 30 to page 22, line 21. Support for new claim 30 can be found in page 7, lines 12-13; page 10, lines 24-26; and page 12, lines 33-36 of the specification.

### Brief Summary of Claimed Subject Matter

The subject matter of claim 1 relates to a multifunctional synthetic bioabsorbable device comprising a synthetic bioabsorbable polymeric matrix with particles of an additive pharmacological agent dispersed therein and **cavities** formed around said particles through **mechanical processing** of a mixture of the matrix and said particles. *See* page 6, line 17 to page 7, line 4; claim 1.

### Claim Rejections — 35 U.S.C. §112

Claims 2-6, 8, 9, 11, 12, 14, 15-17, 19, 20, 23, and 25-27 stand rejected under 35 U.S.C. §112, second paragraph as being allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 has been amended to recite “[t]he multifunctional device of claim 1, wherein the device has reduced Young’s modulus and increased elasticity in comparison with a device comprising the same synthetic bioabsorbable polymeric matrix and processed in the same way but comprising no particles of pharmacological agent” because of a cavitated spindle-

shaped or oval-shaped porous structure resulting from the processing of said mixture.” The amendment is at least supported by the disclosure in Example 2, page 19, line 30 to page 22, line 8. The amended claim 2 now recites the kind of modulus and with respect to what the modulus is reduced and the elasticity is increased. Claim 3 has been amended to delete the phrase “any derivative of these.” Claim 25 has been amended by replacing “it” with “the said multifunctional device.” Claim 27 has been cancelled, rendering this rejection moot. Claims 2-6, 8, 9, 11, 12, 14, 15-17, 19, 20, 23, and 25-26 are fully in compliance with 35 U.S.C. §112, second paragraph. Applicants respectfully request the withdrawal of the rejections of these claims.

#### **Claim Rejections — 35 U.S.C. §101**

Claim 27 was rejected under 35 U.S.C. §101 for being an improper process claim. Claim 27 has been cancelled, rendering the rejection moot.

#### **Claim Rejections — 35 U.S.C. §103**

Applicants respectfully traverse the rejections of claims 1-27 as being rendered obvious by Fischer et al. (EP 1157708; “Fischer”) in view of Vogt et al. (US 2008/0058733; “Vogt”) under 35 U.S.C. §103(a).

Claim 1 recites a multifunctional synthetic bioabsorbable device comprising: a synthetic bioabsorbable polymeric matrix, particles of an additive agent in the form of pharmacological agent, **cavities** induced around the particles of the additive agent dispersed in said synthetic bioabsorbable polymer matrix, said cavities existing in said matrix as a result of **mechanical processing** of a mixture of the matrix and said particles.

Fischer, according to the Examiner, discloses a multifunctional device comprising a synthetic bioabsorbable polymer matrix and particles of an additive agent in the form of pharmacological agent (paragraph [0007]). The Examiner acknowledged that Fischer does not teach the cavities induced around the particles of the additive agent dispersed in said synthetic bioabsorbable polymeric matrix, said cavities existing in said matrix as a result of **mechanical processing** of a mixture of the matrix and said particles. Vogt, according to the Examiner, discloses cavities encapsulating an additive agent (paragraph [0009] and [0010]). The Office Action then concludes that it would have been obvious to one of ordinary skill in the art to induce cavities around the additive agent of the device of Fischer in view of Vogt.

Vogt, however, does not teach or suggest cavities existing around the particles of the additive agents in a polymer matrix **as a result of mechanical processing** of a mixture of the polymer matrix and said particles as recited in claim 1. Vogt describes stable composites formed by homogeneous polymer mixtures of one or more hydrophobic polymers, one or more hydrophilic polymers, and slightly water-soluble antibiotics (page 2, paragraph [0009]). When the composites of Vogt were introduced into an aqueous environment, the hydrophilic polymer dissolved, creating cavities encapsulating the slightly water-soluble antibiotics particles in the remaining hydrophobic polymer matrix (page 2, paragraph [0009]). In other words, the cavities of Vogt encapsulating particles of additive agents were formed as a result of the hydrophilic polymer in the composite dissolving in an aqueous environment, NOT as a result of **mechanical processing** of a mixture of a polymer matrix and particles of additive agents as recited in the instant claim 1. Thus, claim 1 (and all claims that depend thereon) is not obvious over Fischer et al. (EP 1157708) in view of Vogt et al. (US 2008/0058733).

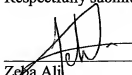
### **Conclusion**

It is respectfully submitted that the present application is now in condition for allowance, which action is respectfully requested. The Examiner is invited to contact Applicants' representative to discuss any issue that would expedite allowance of the subject application.

Any fees for extension(s) of time or additional fees that are required in connection with the filing of this response are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is authorized to charge any such required fees or to credit any overpayment to Kenyon & Kenyon LLP Deposit Account No. 11-0600.

Respectfully submitted,

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Zeba Ali  
Reg. No. 51,392

Kenyon & Kenyon LLP  
1500 K Street, N.W., Suite 700  
Washington, D.C. 20005  
Telephone: (202) 220-4200  
Facsimile: (202) 220-4201